REMARKS

Claims 1, 29, 48, and 49 have been amended for grammatical purposes and to remove the "auxiliary substance." These claims have also been amended for grammatical purposes.

Election/Restriction

The Examiner states that "the methods of claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-33, and 46-48 do not relate to the same single general inventive concept . . . as the originally elected method of administering an antibody specific for Lewis Y during surgery." As discussed in the Response to the Restriction Requirement, dated May 24, 2007, the Restriction Requirement was improperly applied for two reasons.

First, in the International phase, the claims were not objected to as lacking Unity of Invention under the Rule 13.1 PCT Standard, thus the Examiner's imposition of a restriction based on Weitz and Nagashino is improper.

Secondly, the combination of Weitz and Nakashino does not establish that the present invention lacks an inventive step. The common inventive aspect of the present invention is administering a carbohydrate tumor associated antigen. Weitz merely mentions "perioperative antibody or cytotoxic therapy" but does not mention tumor associated antibodies or carbohydrate tumor associated antibodies. Furthermore, Weitz's discussion of the perioperative application of antibodies is purely speculative (page 332, col. 2, lines 17-19, "perioperative antibody or cytotoxic therapy may prevent tumor cell implantation. These hypotheses have to be evaluated in further studies.") (emphasis added). Likewise, Nakashino does not disclose antibodies against a carbohydrate tumor associated antigen. From Weitz, one of skill might apply any antibody at any time spanning from the last doctor's office visit prior to surgery until the patient checks out after surgery. From Nakashino, one of skill would apply antibodies directed to CD44H and/or β_1 integrin.

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Thus one of skill would not select a carbohydrate tumor associated antigen from the numerous TAAs available, nor would they expect that said carbohydrate tumor associated antigen, when applied *during* or *up to 4 hours prior to* surgery, would prevent metastases. Thus, claims 1-48, and claim 49 should be rejoined.

Priority

Applicants enclose a translation of the priority document Austria A-1217/2002 under 37 C.F.R. §41.154.

Objection

The Examiner objects to claim 49 as being drawn in the alternative to the subject matter of a non-elected invention. Applicants submit that the Restriction Requirement is being improperly applied in this instance. As discussed above, claim 49 has a special technical feature over Weitz and Nakashino. Thus, Applicants request that the objection be withdrawn.

35 U.S.C. §102(b)

Goldenberg

The Examiner rejects claim 49 as anticipated by US Patent No. 5,716,595 (hereinafter Goldenberg). The Examiner states that Goldenberg "teaches methods for the intraoperative treatment of tumors comprising administering-tumor associated antibodies to patients during surgical treatments." The Examiner further states that such an administration is both "a method for close-range tumor detection and treatment during an operative, intravascular or endoscopic procedure. The method comprises injecting a patient . . . with an effective amount of a labeled protein."

Applicants object to the Examiner's characterization of the method disclosed in Goldenberg. Applicants first object that the method "for the intraoperative treatment of tumors" is the same type of treatment as disclosed in the present method. The method disclosed by Goldenberg is directed to "photodynamic detection" or "photodynamic therapy." (Goldenberg, col. 9, lines 1-

2). Neither method induces antibody-dependent cellular cytotoxicity effector function or complement dependent cytotoxicity effector function. This observation is supported by the dosage used in the Goldenberg method. Goldenberg uses a parenteral administration of "0.01 to 20 mg, preferably about 0.05 to 5 mg, of labeled antibody fragment or labeled antibody." (Goldenberg, col. 15, lines 45-46). In contrast, the present invention utilizes "a high dose of at least 50 mg, preferably at least 100 mg, most preferred at least 200 mg" of antibody per patient. (Specification page 15, lines 12-15). Thus, the amount of antibody disclosed in Goldenberg would not be sufficient to induce antibody-dependent cellular cytotoxicity effector function or complement dependent cytotoxicity effector function. Thus Goldenberg does not anticipate the present invention.

Neither would one expect that additional antibody would be beneficial based on the disclosure of Goldenberg. Goldenberg discloses that the level of circulating antibody should be reduced so as to minimize "interference of background radiation with the short-range detection process." (Goldenberg, col. 15, line 14-15). In comparison, the present invention gives an overabundance of antibody, "to saturate the relevant surface antigens of the tumor cells." (Specification, page 15, line 12). Thus, because Goldenberg does not induce the antibody-dependent cellular cytotoxicity effector function or complement dependent cytotoxicity effector function and in fact teaches away from using large amounts of the antibody, Goldenberg neither anticipates, nor renders obvious the present invention.

The Examiner also states that the "compositions of tumor-associated antibody conjugates of US Patent No. 5,716,595 . . . are structurally and materially indistinguishable from the instantly recited composition." Applicants submit that the Examiner's interpretation is in error. The Examiner states that "the instant specification at page 13 exemplifies the antibodies of the invention as including antibodies of any type and teaches that antibody fragments, conjugates, homologues or derivatives may be used." (citations omitted). On page 13 the Specification discusses "antibodies of any type" as being "monospecific or polyspecific monoclonal antibodies." (Specification, page 13, lines 17-22). In contrast, an "antibody derivative" is "selected from the group of antibody fragments, conjugates, homologues, or derivatives."

(Specification, page 13, lines 31-32). Since the claims recite "antibody" rather than "antibody derivative" the Examiner's interpretation of the term "antibody" to include "fragments" or "conjugates" is plainly wrong. Thus, Goldenberg, directed to a labeled antibody, does not anticipate the present invention.

Applicants request that the rejections based on Goldenberg be withdrawn.

Ferrari

The Examiner rejects claim 49 as being anticipated by US Patent Number 6,107,102 (hereinafter Ferrari) under 35 U.S.C. §102(b). The Examiner states that it since the Ferrari discloses whole antibodies comprising an Fc domain, the Fc domain "activates antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions."

Applicants submit that the present invention consists of an antibody directed against a tumor-associated antigen and at least one pharmaceutically acceptable carrier selected from the group consisting of a buffer, a salt and a preservative. None of these substances comprise the "device" which is the subject of the invention of Ferrari. In Ferrari, therapeutic agents are never delivered without the microdevice. Thus, the microdevice of Ferrari is essential to the invention, and does not suggest or anticipate the administration of the presently claimed method.

Furthermore, as discussed above, the Examiner's interpretation of the term "antibody" to mean a "fragment" or a "conjugate" is contrary to the Specification. Thus, the Examiner's argument that the "compositions of tumor-associated antibody conjugates of US Patent No. 6,107,102 . . . are structurally and materially indistinguishable from the instantly recited composition" is also in error.

Thus, the present invention is not anticipated by Ferrari, nor is it suggested by Ferrari. Applicants respectfully request that the rejection be withdrawn.

Golub

Applicants enclose sworn translation of the priority document concurrently with this paper, thereby obviating this rejection.

Double Patenting

Applicants request that the double patenting rejection be addressed once there is allowable subject matter.

35 U.S.C. §112 Indefiniteness

The Examiner rejects claim 49 for the recitation of "an auxiliary substance." Applicants have amended the claims to remove the term, thereby obviating the rejection. Applicants request that the rejection be withdrawn.

Conclusion

Favorable action and early allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

#47,604

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